UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TYLER DIVISION

SHERRY L. JONES	§	
Plaintiff	§	
	§	
vs.	§	**CIVIL ACTION NO. 6:07CV455**
	§	
BLACKSTONE MEDICAL, INC., SCT, INC., and DISANTO TECHNOLOGY, INC.	§	
Defendants.	§	

DEFENDANT, SCT, INC.'S,
REPLY TO PLAINTIFF'S RESPONSE TO MOTION TO DISMISS

THE HONORABLE JUDGE:

COMES NOW, **DEFENDANT, SCT, INC.,** in the above-entitled and numbered cause and files this, its Reply to Plaintiff's Response to Motion to Dismiss, and respectfully shows the Court as follows:

I. SCT, INC. is protected under the BAAA.

1. Plaintiff's first argument in opposition to the Motion to Dismiss is that SCT is not protected under the BAAA. This argument contradicts the plain language of the statute. As SCT pointed out in its motion to dismiss, the BAAA includes very specific provisions that define exactly who is, and who is not covered by the statute. According to the precise definitions outlined in the BAAA, SCT is a biomaterials supplier protected by the statute, in that it "directly or indirectly supplies a component part or raw material for use in the manufacture of an implant." 21 U.S.C. 1602(1). The BAAA does not exclude suppliers of parts that were designed or manufactured for use in a specific medical device.

2. The fact that Congress made a finding that "most...[implantable] medical devices are made with raw materials and component parts that... are not designed or manufactured specifically for use in medical devices," and then specifically wrote the statute to include all biomaterial suppliers–

whether or not they supplied materials specifically for medical devices– only emphasizes that suppliers like SCT are protected by the statute. 21 U.S.C. 1601; Whaley v. Morgan Advanced Ceramics, Ltd., 2008 WL 901523 at *3 (D. Colo. March 31, 2008) (rejecting as "unsupported by the language of the BAAA the plaintiff's... argument that the BAAA only protects component part manufacturers regarding components not designed or manufactured specifically for use in a medical device....").

3. Further, in Docket No. 75, this Court has issued an Order granting DiSanto's Motion to Dismiss on the same issues. SCT, like DiSanto, is a biomaterials supplier that is protected by the statute because it supplies a component part for use in the manufacture of an implant. Thus, the plaintiff's first argument must be rejected.

II. The component parts supplied by SCT met all applicable contractual requirements and specifications.

4. Plaintiff admits that discovery has been conducted, and that there is not a further need for written discovery. Plaintiff only argues that she needs additional time to allow the metallurgist to conduct destructive testing to determine whether the screws met the specifications required by Blackstone; she must wait until after MedSource has appeared and has had an opportunity to inspect the device at issue.

5. The purpose of the BAAA is to protect biomaterials suppliers, such as SCT, from incurring the significant costs associated with products liability litigation, and specifically provides for the removal of such defendants on a motion to dismiss. 21 U.S.C. 1601; 1605. The statute allows for limited discovery on the issue of noncompliance with contractual specifications only where the court makes a determination that, "to the extent raised in the pleadings and affidavits... the defendant may be liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications..." 21 U.S.C. 1605(c)(3). Nothing in the Plaintiff's pleadings would allow this Court to make such a determination. To the contrary, the record on the Motion to Dismiss establishes just the opposite– that there is no basis to claim that the component part manufactured by SCT failed to comply with contractual specifications.

6. SCT supplies component parts to Blackstone, a manufacturer of implants, pursuant to purchase orders. Blackstone defines precisely what SCT is to supply, including exact dimensions

of the component, as well as certified subcontractors who will provide the raw material for the component. SCT does not manufacture the raw material for the component part. In fact, the subcontractor who does manufacture and supply the raw material to SCT must submit a Certification with the material, stating that it complies with Blackstone's specification.

7. Blackstone, as the manufacturer of the implant, assumes all responsibility for ensuring that the component part complies with specified requirements, as well as the responsibility for creating and maintaining records that reflect such compliance. 21 C.F.R. 820. Blackstone may not release any implant for distribution until it has inspected and accepted all component parts, documented its acceptance, and retained all records of compliance. 21 C.F.R. 820.80(d). Blackstone must create and retain "device master records" and "device history records" for an implant, which reflect all specifications, quality assurance procedures, certifications, and acceptance records which demonstrate that the implant and all component parts are manufactured in accordance with the specifications. 21 C.F.R. 820.181; 820.184. All component parts supplied by SCT to Blackstone Medical were inspected and accepted by Blackstone Medical.

8. The plaintiff has no basis on which to claim that the component part manufactured and supplied by SCT did not comply with Blackstone's specifications. The fact that the plaintiff plans to consult a metallurgist and conduct destructive testing only highlights the fact that the plaikntiff is making baseless claims. As SCT does not manufacture the raw material for the component part, the opinions of a metallurgist will have no bearing on the issue of SCT's compliance with contractual specifications. Similarly, a physical examination of the implant has already been conducted. The only issue relevant to SCT's liability is whether Blackstone inspected and accepted the component part as being in compliance with the manufacturer's specifications, and this was done.

9. SCT has incurred high costs to defend itself against the plaintiff's claims. The purpose of the BAAA and the FDA regulations cited above is to place the burden of ensuring compliance on the implant manufacturer, and to prevent biomaterials suppliers from incurring litigation costs. The plaintiff's arguments directly contradict the purpose and intent of both the federal statute and its accompanying regulations.

III. The Fifth Amended Complaint against SCT must be dismissed.

10. The BAAA specifically provides that "the court shall grant a motion to dismiss" filed by a biomaterials supplier unless the court determines that the supplier is liable as a manufacturer, as a seller, or for furnishing component parts that failed to meet contractual requirements, as described above. In the instant case, SCT– a biomaterials supplier– furnished a component part that met with all contractual requirements and specifications. As such, Plaintiff's Fifth Amended Complaint against SCT must be dismissed in its entirety with prejudice.

11. The BAAA precludes any finding of liability on the part of SCT for harm caused by an implant. Wherefore, the Defendant, SCT, respectfully moves this Court to grant its Motion to Dismiss, with prejudice.

Respectfully submitted,

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ATTORNEY FOR DEFENDANT

CERTIFICATE OF SERVICE

I hereby certify that on this the 22nd day of December, 2008, a true and correct copy of the foregoing instrument was served upon all parties via electronic mail.

/s/ Reid Wm. Martin
REID WM. MARTIN